Northwest Lions Eye Bank
A program of Lions Sight & Hearing Foundation of Washington and Northern Idaho

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December 29, 1999

Dockets Management Branch (HFA-305)
The Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S; Suitability Determination for Donors of Cellular and Tissue-Based Products; 64 Federal Register 189; September 30 1999.

To Whom It May Concern:

The Northwest Lions Eye Bank (NLEB) respectfully submits the following comments in reference to the FDA's proposed rules regarding suitability determination for donors of human cellular and tissue-based products.

We would like to commend the FDA for the success of the initial final rule as it applies to maintaining the safety of corneal transplant tissue. Since the initial publication and enforcement of regulations governing the screening of cornea donors, over 200,000 corneas have been transplanted without a single documented incident of systemic infectious disease transmission. In light of this success we encourage the FDA in any current or future rule-making to avoid arbitrary or unnecessary additions to corneal donor screening that only serve to increase the cost and decrease the supply of quality corneal transplant tissue.

While we have several concerns regarding the proposed rules we primarily want to shed some factual light on the necessity and benefit of performing medical social history interviews for all cornea donors, including those that are obtained under legislative consent. The FDA has received numerous comments against requiring this screening for legislative consent donors with claims that this will greatly reduce the supply of corneal tissue, create an undue burden on donor families, or require use of a screening tool that "lacks...validity." **NLEB strongly refutes these claims and urges the FDA to maintain the proposals that would require medical social history interviews for all donors.**

Over the past three years our Eye Bank has increased our supply of corneal tissue from 700 corneas per year to over 2000 corneas per year. We have done this while performing a medical social history interview on every donor prior to release of any tissue for transplant.. Not only have we found these interviews to provide crucial medical and social screening information, we have also found this direct contact with donor families to be encouraging and enhancing to the donation process. We are aware from experience that not every interview provides conclusive, reliable information, but from this same experience we know that many times over we have received critical screening information using this tool. **It is the position of NLEB that it would be medically negligent not to use this screening tool on all cornea donors.**

Our experience and position regarding this issue is shared by the majority of Eye Banks across the country who, for various practical and political reasons have not been as vociferous as the minority who still recover and distribute corneas without using the medical social history interview as a screening tool. Furthermore, from our experience we have found that those donors who do come from medical examiner's or coroner's offices have an increased

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likelihood of high risk behavior. Also, at the encouragement of professionals who work at the largest medical examiner's office in our state, we do not rely solely upon the data their investigations and autopsies provide to determine the existence of high risk behavior. We have been specifically informed that medical examiner investigations focus solely on determining the cause and manner of death and that peripheral social behavior or medical history that do not factor into the cause of death are not investigated. We are confident that this is the practice of most medical examiners in this country and therefore cannot rely solely upon autopsy reports to determine the suitability of corneal tissue.

Other specific comments we have regarding the proposed rules are as follows:

- The feasibility of testing for TSE in donors of corneal tissue: At the present time, a brain biopsy is not a feasible method of screening cornea donors for TSE. The time required for an autopsy to be performed and results confirmed would eliminate the possibility of corneas being used for transplant. Additionally, the cost of brain autopsies would likely double the cost of providing corneas for transplant. The medical social history interview is one of the best tools we have for TSE and CJD screening and it should be used on all cornea donors.
- Storage of corneal tissue as impacted by Section 1271.65 (a): The proposed definition would require additional refrigerator storage units for "quarantined" tissue. This would not improve tissue quality or safety and would represent a large space and cost burden. We recommend that the definition of "quarantined" tissue remain as it is in the current final rule.
- The use of pre-transfusion blood samples as impacted by Section 1271.80 (b): Pre-infusion blood samples many times provide the most scientifically accurate serology results, therefore, **we request the deletion or revision of any rules that would prohibit them from being used.**

Again NLEB appreciates the opportunity to comment on these proposed rules. We look forward to continuing to work with the FDA to ensure that the supply of corneal tissue for transplant remains safe.

Sincerely,

Monty M. Montoya
Eye Bank Director

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